REMARKS

Claims 1, 4 – 12 and 15 – 20 are currently pending. Of these, Claims 1, 15, and 16 are independent. In the most recent Office Action, the Examiner rejected all pending claims on the alleged ground that the subject matter of these claims would have been obvious to a person of ordinary skill in the art from a combination of parts of U.S. Patent No. 5,498,788 to Zmitek et al. ("Zmitek"), the Buckton et al. publication ("Buckton"), U.S. Patent No. 5,585,115 to Sherwood et al. ("Sherwood"), and the Czap publication.

These rejections are respectfully traversed. Favorable reconsideration is requested in view of the above amendments and following remarks.

Claims 1, 15, and 16 each call for, *inter alia*, a pharmaceutical tablet which comprises amoxicillin, clavulanic acid and silicified microcrystalline cellulose or "SMCC." The claims further specify that the tablet includes no disintegrants or superdisintegrants except the silicified microcrystalline cellulose. In other words, SMCC is the sole disintegrant in the tablet. This is not suggested by the cited references, or by any purported combination of parts thereof.

Zmitek teaches the use of multiple disintegrants or superdisintegrants – microcrystalline cellulose (MCC) and crospovidone – in combination with one another in both Examples 10 and 11. The Examiner counters this by suggesting that the crospovidone in Zmitek is "optional." For this, he points to Col. 6, line 10 – 12 of Zmitek, which states that, in certain galenic embodiments, "adjuvants such as disintegrators, fillers, coloring agents, sweetening agents, etc. may be added if necessary."[1] This argument has no merit.

Zmitek's comments about the "permissibility" of including disintegrants, in context, assumes two extremes – none and some; and it is very clearly an expression that, depending on the form, (a pill, a gelatin capsule, or even an injectable formulation), certain of the recited adjuvants might be necessary, or the might not be. It depends upon the particular type of formulation to be prepared. But a person of ordinary skill would

[1] A "galenic formulation" is a pharmaceutical formulation which has been compounded to optimize its bioadsorption.

not have understood this to imply that any particular one of the recited types of adjuvants would, or would not be, needed in any specific galenic form (capsule, tablet, cachet, injections, and so forth). Nor can it reasonably be taken as a suggestion that, in those formulations where disintegrants would be needed, such as in a pill to be dissolved rapidly in the mouth or stomach, for example, that only a single particular type of disintegrant would suffice in any particular circumstance.

This is especially evident from the fact that Zimtek itself only teaches use of multiple disintegrants in those formulations, such as pills and the like, where disintegrants are needed. Nowhere does Zmitek even remotely suggest that, when needed, only a single particular disintegrant would suffice. The matter of the compatibility of a particular type of disintegrant with a particular active pharmaceutical for optimum bioavailability (see note 1 infra), or whether such compatibility would allow the formulator to dispense with the conventional "shotgun" approach of using multiple disintegrants, is not even hinted at in Zmitek. A passing reference to the fact that some food dishes, depending on what they are, might need to have "seasonings," is not a fair or reasonable suggestion that a specific shrimp dish will be adequately seasoned with only garlic.

A person of ordinary skill looking to Zmitek for guidance in the formulation of a tablet comprising amoxicillin and clavulanic acid with optimum bioavailability would have quickly focused on Examples 10 and 11, which are the only parts that pertain to tablets containing amoxicillin and clavulanic acid. Both examples use multiple disintegrants. Both use microcrystalline cellulose (MCC) and crospovidone, in combination with one another.

Zmitek simply does not suggest the subject matter of independent Claims 1, 15, and 16. In fact, Zmitek effectively teaches away from the subject matter of the claims. By teaching use of multiple disintegrants for optimum bioavailability of the active ingredients amoxicillin/ clavulanic acid, Zmitek hardly can be said to teach the

sufficiency of using only one. As for the other references, none overcomes the aforementioned deficiencies of Zmitek.

Thus, independent Claims 1, 15, and 16 patentably distinguish over Zmitek, combined with Buckton, Sherwood, and Czap. Moreover, since the dependent claims include all of the limitations of the independent claims, they also patentably distinguish over the cited references for at least the same reasons.

In light of the foregoing, the present amendment is believed to place the application in a condition for allowance and entry of the foregoing amendments and allowance of Claims 1, 4 – 12 and 15 – 20 is respectfully solicited.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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